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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,056	08/26/2003	Jeff R. Justis	MSDI-77/PC753.00	2957
53196 7590 04/03/2009				
MEDTRONIC				
Attn: Noreen Johnson - IP Legal Department				
2600 Sofamor Danck Drive				
MEMPHIS, TN 38132				
EXAMINER				
STEWART, ALVIN J				
ART UNIT		PAPER NUMBER		
3774				
MAIL DATE		DELIVERY MODE		
04/03/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/648,056

**Applicant(s)**

JUSTIS ET AL.

**Examiner**

Alvin J. Stewart

**Art Unit**

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 April 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 5-7, 11-14, 44-47, 51-57, 61-64, 67 and 69 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1, 5-7, 11-14, 44-47, 51-57, 61-64, 67 and 69 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-949)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

NOTE: The Examiner withdrew the finality of the previous Office Action in order to add a 112, 1<sup>st</sup> paragraph rejection over new matter. However, the Examiner maintains the previous rejection.

Regarding the response to the amendment filed on 04/22/08 the examiner still believes that the prior art read on the claims. For example, the applicant's representative discloses that the outer shell 30 in Trieu is not taught to rigidly fix support members 7 at a volume.

Additionally, the Applicant's representative discloses that if Baumgartner were somehow modified to include means for rigidly fixing support members 7 at a volume, then support members 7 would not elastically deform.

Regarding the outer shell and the volume, the Examiner does not understand why the Applicant's representative is arguing on how the outer shell cannot rigidly fix the support members. For example, as previously discloses in the last office action, the outer shell that was injected into the intervertebral disc as a fluid (see col. 5, lines 20-67) is capable of covering the whole implant and all the implant voids to prevent expulsion. As shown in col. 5, lines 40-46, the outer shell provide flexibility to the implant.

Regarding the volume, the Examiner interpreted the volume as the whole resected patient's disc area. Therefore, the outer shell 30 would fix the volume of the elastic support member 7 of Baumgartner.

Regarding the elastic deformation, as mentioned above col. 5, lines 20-67 clearly disclose that the outer shell is capable of having flexibility. Additionally, col. 6, lines 62-67 clearly discloses elastic and flexible materials.

Regarding the Applicant's arguments that the support members elastically deform under stress, the Examiner wants to point out that those limitations are nowhere found in the claims. The only thing related to compression is on all the independent claims disclosing the following "to compress cancellous bony tissue". The Examiner is interpreting the above phrase that the support members are capable of compressing cancellous bony tissue and not that the support members are compressing.

Regarding the Baumgartner and Trieu references, the Examiner still believes that the 103 rejection is still proper and reads on all the structure limitations of the claims. For example, the filling material that rigidly fixes the reduction elements in engagement with one another is disclosed in the Trieu reference. Trieu discloses an anchoring outer shell made of a variety of biocompatible materials for the purpose of anchoring the implant within the disk and fill all the open voids in the implant. For the above reasons the examiner believes that the previous rejection is proper.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-7, 11-14, 44-47, 51-57, 61-64, 67 and 69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitations "rigidly fixing" are not in the original disclosure of the application. The Applicant's representative must enter limitations that are in the original disclosure.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-7, 11-14, 44-47, 51-57, 61-64, 67 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner US Patent 5,755,797 in view of Trieu US Patent 6,620,196 B1.

Baumgartner discloses an intervertebral reduction system comprising a plurality of reduction elements positionable in an intervertebral space adjacent one another, the elements include a spherical shape, an exterior surface and a cavity extending through the reduction element. However, Baumgartner does not disclose a material filling the voids and the reduction elements made of PMMA.

Trieu teaches an implant core (15) inserted within the vertebral disc having upper, lower, and lateral voids surrounding the implant, wherein an outer shell (30) fills in the voids for the purpose of anchoring and fixing in place by the outer shell (see col. 5, lines 20-28).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Baumgartner reference with the outer shell of the Trieu reference in order to anchor and fix in place the outer shell.

Regarding claims 6, 46 and 57, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the material property of the Baumgartner reference because Applicant has not disclosed that the PMMA material provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the polyethylene material of the Baumgartner reference because the material is capable of absorbing the forces exerted in the body and they are biocompatible.

Therefore, it would have been an obvious matter of design choice to modify the Baumgartner reference to obtain the invention as specified in claims 6 and 46.

Regarding claims 7, 47, the Examiner interpreted the exterior surface features to facilitate engagement as follow: the exterior surface feature is the whole exterior circular surface of element 7 in Figure 6 because the device is a sphere then the device has a high surface area to facilitate the engagement between adjacent reduction elements.

Regarding claims 11, 51 and 61, see Figure 6 disclosing the cavity.

Regarding claims 12, 52 and 62, the use of the phrase: "for post-operative maintenance and stability..." has been given weight but the Examiner is only looking for a device that is capable of performing the above function (see col. 14, lines 32-49). Finally, the Examiner is interpreting the "post-operative maintenance" as after the implant 7 in the Baumgartner reference and/or element 15 in the Trieu reference are implanted but before element 30 (Trieu) is injected.

Regarding claims 12, 13, 52, 53, 60, 62 and 63, Trieu teaches an intervertebral implant comprising a reduction element (15) covered by a material placeable (30) in the intervertebral space around the reduction element for the purpose of anchoring the implant to the wall of the vertebral body and avoid the expulsion of the implant from the disc cavity, promote the growth of fibrous tissue and provide mechanical support to the disc (see col. 5, lines 20-67; col. 6, lines 62-67; and col. 7, lines 1-32).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Baumgartner reference with the material placeable in the intervertebral space around the implant in order to anchor the implant to the wall of the vertebral body and avoid the expulsion of the implant from the disc cavity, promote the growth of fibrous tissue and provide mechanical support to the disc.

Regarding claims 13, 53 and 63, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the material property of the Trieu reference because Applicant has not disclosed that the PMMA material provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the plurality of polymeric materials disclosed in the Trieu reference because the material is capable of been bioabsorbable, absorb the forces exerted in the implant and anchor the implant to the disc cavity.

Therefore, it would have been an obvious matter of design choice to modify the Trieu reference to obtain the invention as specified in claims 13, 53 and 63.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alvin J Stewart/  
Primary Examiner, Art Unit 3774

March 30, 2009.